REMARKS

Claims 1-27 are pending in the application. Claims 1-16 and 22-27 are withdrawn from consideration. Claims 17-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the reasons set forth below, respectful reconsideration of the application is requested.

Strong Presumption of an Adequate Written Description

As noted in MPEP 2163, citing Wertheim, 541 F2d at 262, 191 USPQ at 96, "There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed."

The Strong Presumption was not overcome

According to the Office Action, claims 17-21 were rejected for lack of a written description because the "...description does not includes all compounds found in claim 17..." In support of this position, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998) was cited. Applicant respectfully submits that the Office Action failed to establish a prima facie case for lack of a written description because neither the case cited nor any other case Applicant is aware of requires that all species described by a genus be specifically disclosed in a specification.

Because issues regarding written description are fact-sensitive, it's important to look more closely at the Eli Lilly case to understand the basis for that decision and what facts would have resulted in a different outcome. The claims before the Lilly Court were related to a microorganism that requires human insulin-encoding cDNA, wherein the cDNA required was described by function rather than by structure. No sequence information was provided in the specification. The Lilly Court cited Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606 for the proposition that a "...description of a genus of cDNA may be achieved by a recitation of a representative number of cDNAs, defined by nucleotide sequences, falling within the scope of

the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." Citing In re Robins, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) the Court noted that "[m]ention of representative compounds encompassed by generic claim language clearly is not required by §112 or any other provision of the statute." Because neither the Lilly case nor MPEP 2163 provide support for the position that all species described by a genus must be specifically disclosed in a specification, a prima facie case for lack of a written description was not provided and the strong presumption of an adequate written description in this specification as originally filed was not overcome.

The Lilly Case and MPEP 2163 support a finding that the written description requirement has been met

In discussing what is required to comply with the written description requirement, the Lilly Court indicated that complying with the written description requirement was analogous to complying with the enablement requirement by:

> ...showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); In re Robins, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by §112 or any other provision of the statute. But where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may provide an implicit description upon which to base generic claim language."); Cf. Gostelli, 872 F.2d at 1012, 10USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); In re Grimme, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) ("[I]t has consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'") (citations omitted).

At page 5, line 19 through page 6, line 2 the generic description from claim 17 can be found as well as support for claim 18. Support for claims 19-21 can be found at page 10, lines 2-12. In addition, FIG. 17 provides nine species that comply with the generic language provided on pages 5-7 and claim 17 which include species: 17 (AO17-79J, AO17-80D, AO17-80K, AO17-50 (A-D), AO24-16 (Q-U), AO24-16 (V-Z), AO17-79 (E-H), AO24-16 (M-P), and AO17-79D.

Finally, the Lilly Court spoke directly to the issue of written description for chemical materials indicating that:

> In claims involving chemical materials generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such a "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define the structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Claims 17-21 define the claimed invention based on structural features rather than function. The supporting descriptive language at page 5 through 6 of the specification describes a generic structure using words rather than an actual chemical structure. However, one skilled in the relevant art reading this language readily understands the structural requirements provided and can readily visualize the generic structure represented. MPEP 2163 citing Lockwood, 107 F.3d at 1572, 41 USPQ 2d at 1966 recognizes that the …"'written description' requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."' (Emphasis added) Application of the teachings of the Lilly Court and MPEP 2163 to the present facts, support a finding that the written description requirement has been met by the current specification.

Claims 17-21 currently stand rejected. For the reasons provided above the rejections of each of these claims is respectfully traversed. In view of the above, it is submitted that claims 17-21 are in condition for allowance. Reconsideration and withdrawal of the rejections are requested. Allowance of claims 17-21 at an early date is solicited.

Should the Examiner have any questions about this submission or should there be other matters which might be readily resolved, the Examiner is invited to telephone the undersigned attorney.

Respectfully submitted,

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